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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/816,653

03/23/2001

Diane Pennica

10716-57/CURA233/GN1885R1

6857

23552

7590

02/24/2005

MERCHANT & GOULD PC

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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/816,653

Applicant(s)

PENNICA ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 36-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 36-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Re: Pennica *et al.*

Date of priority: 03-23-2000

Request for Continued Examination

The request filed on 11-15-2004 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/816653 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 1, 3, and 36-49 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 1, 3 and 36-49 remain rejected under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph (enablement), because the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons of record (Actions mailed 03/17/2003 and 11/14/2003). Initially, applicants discuss (Response, page 4) the importance of Wnt expression and its link to cancer while summarizing structural features common to Wnt family members (i.e. cysteine-rich and glycosylated). Applicants also point out some observations regarding mSTRA6 such as being identified as upregulated or that it codes for a very hydrophobic membrane protein. Applicants further note that mSTRA6 is an important molecule

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in cellular proliferation and differentiation (Chazaud *et al.* 1996, IDS). Applicants reiterate that Wnt induced upregulated mSTRA6 was understood at the time of the present invention to be a candidate gene involved in the tumorigenic process. Applicants reiterate that differential expression regulated by Wnt-1 expression demonstrates that hSTRA6 is a *candidate* gene for diagnosis and therapeutic use, particularly in cancer.

These arguments have been carefully considered but are not found persuasive. First, with regards to the Chazaud reference, the reference only suggests that mSTRA6 may control aspects of limb development over a time frame extending from the early stages of limb bud patterning to the late gestational ossification process. The reference further notes that the class of protein encoded by the Stra6 gene, as well as its cellular location are unknown (page 72). Thus, while mSTRA6 may be important to cellular proliferation and differentiation, such an assertion is not specific because many other expressed genes are also important to cellular proliferation and differentiation, and the reference fails to provide any information regarding the claimed hSTRA6 protein. Furthermore, the Office has previously acknowledged such comparisons and has maintained that any asserted utility based on homology does not permit extrapolation to biological function or use thereof. The claims are drawn to a novel hSTRA6 protein molecule, not mSTRA6 protein molecule. Also, the office has previously considered hSTRA6 upregulation in Wnt-1 expressing cells in-vitro (page 82). However, the claims are drawn to hSTRA6 *polypeptides*, and there is no evidence to suggest that the differential expression patterns observed on page 82 of the disclosure would reasonably provide a diagnostic and or therapeutic utility for the claimed invention. Thus, for the reasons of record and for the reasons set forth above, applicant's arguments are not found persuasive and the rejection is maintained.

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Claims 1, 36-38, and 40-42 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record (Actions mailed 03/17/2003 and 11/14/2003). Applicant's arguments are substantially similar to those presented earlier (see Response filed 08-18-2003, pages 7-9) and are not found persuasive for the reasons of record.

Claim 47 remains rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. This is a new matter rejection. Applicant argues that amendment of the claim renders the rejection moot. This is not found persuasive. Claim 47 still recites yellow fluorescent protein. As set forth previously, there does not appear to be support for the term "yellow fluorescent protein". Additionally, it is assumed for examination purposes that recitation of "RFP" and "BFP" in Table C refer to red fluorescent protein and blue fluorescent protein, respectively. If this is an incorrect assumption, then it should also be noted that there is no support for red fluorescent protein and blue fluorescent protein. Applicants have not responded to the latter questioning.

Claim 1 remains rejected under 35 U.S.C. 102(e) as being anticipated by any one of the following:

(1) Pennica *et al.* US Patent Application No: 20020156252A1, Prior Filing Date: 01-13-2000.

(2) Pennica *et al.* US Patent Application No: 20020173461A1, Prior Filing Date: 01-13-2000.

(3) Baker *et al.* US Patent Application No: 20030149239A1, Prior Filing Dates: 1997, 1998.

(4) Baker *et al.* US Patent Application No: 20030187201A1, Prior Filing Dates: 1997, 1998, 1999.

(5) Baker *et al.* US Patent Application No: 20030187202A1, Prior Filing Dates: 1997, 1998.

(6) Baker *et al.* US Patent Application No: 20030187203A1, Prior Filing Dates: 1997, 1998.

Each of the above references teach an isolated polypeptide comprising an amino acid sequence having at least 99% sequence identity to SEQ ID NO:2. Applicants argue that in contrast to the Blast analysis provided, the references only disclose a polypeptide having 2 amino acid changes, for example, having less than 99% identity. This argument has been considered but is not found persuasive. Applicants have not clearly set forth the reasoning to explain why a 2 amino acid difference provides less than 99% identity. The references clearly disclose 99% identity over the entire polypeptide, which anticipates the claims. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

No claim is allowed.

Conclusion

This is a continuation of applicant's earlier Application No. 09/816653. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

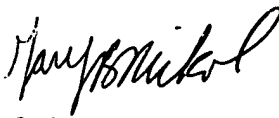
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN


GARY NICKOL
PRIMARY EXAMINER